



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 06/23/2017

Subject: Efficacy Review for Andes, EPA Reg. No. 777-127
(DP Barcode: 438703, E-Submission: 17718)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy / Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser LLC
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium saccharinate.....	0.10%
Ethyl alcohol	58.00%
<u>Other Ingredients</u>	41.90%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment with efficacy data

Currently registered efficacy claim(s): hospital and healthcare disinfectant (bactericidal, virucidal, fungicidal), mildew/fungistat and deodorizer for use on hard, non-porous surfaces; additionally, it is a non-food contact sanitizer for soft surfaces and hard, non-porous surfaces.

Requested action(s): Add disinfection claims against additional bacteria, viruses and fungi on soft surfaces.

Documents considered in this review:

- Letter from applicant to EPA dated March 1, 2017
- Data Matrix (EPA Form 8570-35)
- 5 efficacy studies (MRID 50167101-50167110)
- Proposed label dated 01/11/2017
- Confidential Statement of Formula (EPA Form 8670-4) dated 06/01/2016.

II PROPOSED DIRECTIONS FOR USE

“Pre-clean surfaces prior to use. Hold can (container) upright 6” to 8” from surface. Spray 3 to 4 seconds until covered with mist. ((Gross)(Heavy soil must be removed prior to application

(To Unlock Cap: Turn counterclockwise (1) (2) (clicks). Lock cap, after use.)

To Deodorize: Spray on surfaces as needed.

To Sanitize: Surfaces must remain wet for (10) (30) seconds then allow to air dry.

To Disinfect: (Surfaces must remain wet for 3 minutes then allow to air dry.) (For Mycobacterium bovis BCG surfaces must remain wet for 6 minutes then allow to air dry) (For (Norovirus), (Hepatitis A virus), (Adenovirus 2), (Fusarium solani) (and) (Mycobacterium bovis BCG (Quant tuberculosis)) surfaces must remain wet for 10 minutes then allow to air dry)

Rinse toys and food contact surfaces with potable water after use.

For surfaces that come in contact with food: Use only on hard, non-porous surfaces and rinse thoroughly with water.

To Disinfect Toys: Use only on hard, non-porous surfaces and rinse thoroughly with water after use.

Surfaces must remain wet for 3 minutes then allow to air dry.) (For Mycobacterium bovis BCG surfaces must remain wet for 6 minutes then allow to air dry) (For (Norovirus), (Hepatitis A Virus), (Adenovirus 2), (Fusarium solani) (and) (Mycobacterium bovis BCG (Quant tuberculosis)) surfaces must remain wet for 10 minutes then allow to air dry)

Rinse child/baby plastic toys, child/baby hard non-porous surfaces and all food contact surfaces with potable water or a damp cloth after use.

To Control and Prevent (the Growth of) Mold & Mildew (and their Odors) (on Hard, Non-porous Surfaces): Apply to pre-cleaned surface. Allow to remain wet for 3 minutes. Let air dry. Repeat applications in weekly intervals or when mold and mildew growth appears.

Fabric Sanitizer: (For spot treatment (2” x 2” area) only.)

To (Spot) Sanitize Soft Surfaces (Fabrics): Spray until fabric is wet. DO NOT SATURATE. Fabric must remain wet for 30 seconds. Let air dry. For difficult odors, repeat application.

To (Control) (Eliminate) odor-causing Bacteria on Soft Surfaces (Fabrics): Spray until fabric is wet. DO NOT SATURATE.

Let air dry. For difficult odors, repeat application. Reapply as necessary.

III STUDY SUMMARIES

1.	MRID	50167101	Study Completion Date:	12/13/16			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442)					
Test Method		Disinfectant Efficacy Testing in the Presence of Organic Soil					
Application Method		Aerosol Spray					
Test Substance Preparation	Name/ID	Formula 1178-172					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	Lot 2147-054, Lot 2147-086 and Lot 2147-151					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		100% polyester fabric carriers, 60 per batch					
Test conditions		Contact time	9.5 min	Temp	19-20°C	RH	43-48%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21671					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Due to contamination present in four subculture vessels for Lot 2147-151 on 9/13/16, testing of was repeated with valid results on 10/5/16. For Lot 2147-054, 1/60 carriers showed growth which were determined to be contaminants (non-test organism) based on Gram stain and biochemical assay information confirmation.					

2.	MRID	50167102	Study Completion Date:	12/13/16			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)					
Test Method		Disinfectant Efficacy Testing in the Presence of Organic Soil					
Application Method		Aerosol Spray					
Test Substance Preparation	Name/ID	Formula 1178-172					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	Lot 2147-054, Lot 2147-086 and Lot 2147-151					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		100% polyester carriers, 60 per batch					
Test conditions		Contact time	9.5 min	Temp	19-20°C	RH	50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21674					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

3.	MRID	50167103	Study Completion Date:		12/13/16		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 10708)					
Test Method		Disinfectant Efficacy Testing in the Presence of Organic Soil					
Application Method		Aerosol Spray					
Test Substance Preparation	Name/ID	Formula 1178-172					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	Lot 2147-054, Lot 2147-086 and Lot 2147-151					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		100% polyester carriers, 60 per batch					
Test conditions		Contact time	9.5 min	Temp	19-21°C	RH	26-49%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21675					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing performed on 9/27/16, resulted in a neutralization confirmation control failure for Lots 2147-086 and 2147-151. All three lots of test substance was repeated using Letheen Broth + 0.75% Lecithin + 3.0% Tween 80 as the neutralizer. The neutralization confirmation controls and testing of Lots 2147-054 and 2147-151 were repeated on 10/19/2017. Testing of Lot 2147-086 was repeated on 10/25/2016. Testing performed on 10/19/16 and 10/25/16, resulted in valid results.					

4.	MRID	50167104	Study Completion Date:		12/13/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Trichophyton mentagrophytes</i> (ATCC 9533)				
Test Method		Disinfectant Efficacy Testing in the Presence of Organic Soil				
Application Method		Aerosol Spray				
Test Substance Preparation	Name/ID	Formula 1178-172				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Lot 2147-054 and Lot 2147-086				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		100% plain cotton weave and 100% polyester fabric, 10 per batch				
Test conditions		Contact time	5 min 9.5 min	Temp	19-20.3°C	RH 26-49%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21619				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing on 9/2/2016 resulted in a neutralization confirmation control failure for both lots of test substance on both carrier types. Testing performed on 9/2/16, is invalid. Testing was performed on 10/28/2016 using secondary neutralization, which resulted in valid test results for both lots of test substance on 100% polyester fabric carriers only. Per Sponsor's request, the protocol was amended to change the exposure time from 5 minutes to 9.5 minutes for the repeat test of both lots of test substance on 100% plain cotton weave fabric carriers on November 16, 2016, which resulted in valid results.				

5.	MRID	50167105	Study Completion Date:		9/21/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza A Virus (H1N1), Strain: A/Swine/Iowa/15/30, Lot# 4, Virus ID # 95				
Test Method		Inactivation of Influenza A Virus in the Presence of Organic Matter on Soft Surfaces				
Application Method		Aerosol Spray				
Test Substance Preparation	Name/ID	Formula 1178-172				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	1836-132 and 1836-133				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		100% cotton and 100% Dacron 54 (i.e. polyester)				
Test conditions		Contact time	10 min	Temp	24.2-25.4°C	RH 22.16-26.83%
Testing Lab, Lab Study ID		Reckitt Benckiser Virology Laboratory, 2012-0045				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The protocol stated that the test materials be incubated at 5-7% CO2. For this assay the reported CO2 range was 1.699-7.459%.				

6.	MRID	50167106	Study Completion Date:		9/21/16		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Human Rhinovirus type 39, Strain 209, Virus ID# 121, (ATCC # VR-340)					
Test Method		Inactivation of Rhinovirus in the Presence of Organic Matter on Soft Surfaces					
Application Method		Aerosol Spray					
Test Substance Preparation	Name/ID	Formula 1178-172					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	1836-132 and 1836-133					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		100% cotton and 100% Dacron 54 (i.e. polyester)					
Test conditions		Contact time	10 min	Temp	24.0-25.4°C	RH	53.99-57.87%
Testing Lab, Lab Study ID		Reckitt Benckiser Virology Laboratory, 2012-0046					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The protocol stated that the test materials be incubated at 5-7% CO ₂ . For this assay the reported CO ₂ range was 1.699-7.459%.					

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy (core strains)

MRID	Organism	Date	No. Exhibiting Growth/Total No. Tested			Average log ₁₀ CFU/Carrier
			Batch 2147-054	Batch 2147-086	Batch 2147-151	
100% polyester fabric carrier, 9.5 minute contact time, RTU, 5% soil load						
50167101	Pseudomonas aeruginosa (ATCC 15442)	9/13/16	1*/60	0/60		6.64
		10/5/16			0/60	5.95
50167102	Staphylococcus aureus (ATCC 6538)		0/60	0/60	0/60	6.32
50167103	Salmonella enterica (ATCC 10708)	9/27/16	0/60			7.67
		10/19/16	0/60		0/60	6.84
		10/25/16		0/60		6.71

* Carriers showing growth which were not confirmed as test organism were determined to be contaminants.

Disinfection – Fungicidal Efficacy

MRID	Organism	Date	Contact Time	Carrier	No. Exhibiting Growth/Total No. Tested		Average log ₁₀ CFU/Carrier
					Batch 2147-054	Batch 2147-086	
100% plain cotton weave and 100% polyester fabric carriers, RTU, 5% soil load							
50167104	Trichophyton mentagrophytes (ATCC 9533)	10/28/16	5 min	polyester	0/10	0/10	6.72
		11/16/16	9.5 min	cotton	0/10	0/10	6.14

Disinfection – Virucidal Efficacy

MRID	Organism	Carrier		Batch 1836-132	Batch 1836-133
			Description	AVG. Rep 1-5	AVG. Rep 1-5
100% plain cotton weave and 100% polyester fabric carriers, 10 min contact time, RTU, 5% soil load					
50167105	Influenza A Virus (H1N1), Strain: A/Swine/Iowa/15/30, Lot# 4, Virus ID # 95	Cotton	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /mL	≤ 0.50 log ₁₀	≤ 0.50 log ₁₀
			Log ₁₀ Reduction	≥ 4.50	≥ 4.50
			Average Dried Virus Control (TCID ₅₀ /0.2mL)	5.00 log ₁₀	
		Polyester	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /mL	≤ 0.50 log ₁₀	≤ 0.50 log ₁₀
			Log ₁₀ Reduction	≥ 3.50	≥ 3.50
			Average Dried Virus Control (TCID ₅₀ /0.2mL)	4.00 log ₁₀	
50167106	Human Rhinovirus type 39, Strain 209, Microbac, Sterling, VA	Cotton	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /mL	≤ 1.50 log ₁₀	≤ 1.50 log ₁₀
			Log ₁₀ Reduction	≥ 3.00	≥ 3.00
			Average Dried Virus Control (TCID ₅₀ /0.2mL)	4.50 log ₁₀	
		Polyester	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /mL	≤ 1.50 log ₁₀	≤ 1.50 log ₁₀
			Log ₁₀ Reduction	≥ 3.25	≥ 3.25
			Average Dried Virus Control (TCID ₅₀ /0.2mL)	4.75 log ₁₀	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50167101 50167102 50167103	Disinfectant, bactericidal	100% polyester fabric carriers	Aerosol Spray RTU	9.5 minutes	5%	None	<ul style="list-style-type: none"> • <i>Pseudomonas aeruginosa</i> (ATCC 15442) • <i>Staphylococcus aureus</i> (ATCC 6538) • <i>Salmonella enterica</i> (ATCC 10708) 	Yes
50167104	Disinfectant, fungicidal	100% plain cotton weave	Aerosol Spray RTU	9.5 min	5%	None	<ul style="list-style-type: none"> • <i>Trichophyton mentagrophytes</i> (ATCC 9533) 	Yes
		100% polyester fabric		5 min				
50167105 50167106	Disinfectant, virucidal	100% cotton and 100% polyester	Aerosol Spray RTU	10 minutes	5%	None	<ul style="list-style-type: none"> • Influenza A Virus (H1N1), Strain: A/Swine/Iowa/15/30, Lot# 4, Virus ID # 95 • Human Rhinovirus type 39, Strain 209, Virus ID# 121, (ATCC # VR-340) 	Yes

VI LABEL COMMENTS

01/11/2017/EPA Reg. No.: 777-127

1. The proposed label claims that the product, Andes, ready to use aerosol spray, is an effective disinfectant against the following on 100% polyester soft surfaces in the presence of 5% organic soil for a 9.5 minute contact time:

Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Andes, ready to use aerosol spray, is an effective disinfectant against the following on soft surfaces in the presence of 5% organic soil for a 10 minute contact time:

Influenza A Virus (H1N1), Strain: A/Swine/Iowa/15/30, Lot# 4, Virus ID # 95
Human Rhinovirus type 39, Strain 209, Virus ID# 121, (ATCC # VR-340)

These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product, Andes, ready to use aerosol spray, is an effective disinfectant against the following on 100% plain cotton weave soft surfaces in the presence of 5% organic soil for a 9.5 minute contact time:

Trichophyton mentagrophytes (ATCC 9533)

These claims are **acceptable** as they are supported by the submitted data.

4. The proposed label claims that the product, Andes, ready to use aerosol spray, is an effective disinfectant against the following on 100% polyester soft surfaces in the presence of 5% organic soil for a 5 minute contact time:

Trichophyton mentagrophytes (ATCC 9533)

These claims are **acceptable** as they are supported by the submitted data.

5. Make the following changes to the proposed label:
 - a. Revise all soft surface (fabric/textile) disinfection claims to indicate efficacy only for 100% polyester surfaces. Supporting efficacy data should be developed with both 100% polyester fabric and 100% plain cotton weave carriers to qualify for soft surface/fabric disinfection label claims.
 - b. In the “**Emerging Pathogens Statement**” section on page 26, add the following statement immediately following the section heading:

“This product is eligible to make certain claims against enveloped, large non-enveloped and small non-enveloped emerging pathogens when used in accordance with the use directions for the supporting virus. Note that for use against small, non-enveloped emerging viruses, the use directions for Feline Calicivirus should be followed.”

- c. In the “**General**” section on page 12, remove “(food)” from the claim “Disinfects hard, non-porous (food)(non-food)(contact)(and)(soft) surfaces in..”.
- d. On page 14 of the purposed label, add “on hard non-porous surfaces” to the claim “(Overall) Disinfection in 3 minutes”.
- e. In the “**USE DIRECTIONS**” section, on page 15, Registrant should indicate “hard, non-porous surfaces” to current “**To Disinfect**” use directions. Additionally, disinfection directions should be updated to include soft surface disinfection directions.
- f. In the “**Soft Surface Disinfection- Germs, bacteria & virus and/or fungi**” section, on page 22, remove “9.5 minute disinfection-viruses” and replace with “10 minutes disinfection viruses”. The qualified time for soft surface virucidal disinfection is 10 minutes.
- g. In the chart on page 24 of the purposed label, remove “9.5 minute disinfection – viruses - soft surfaces” and replace with “10 minutes disinfection - viruses-soft surfaces”. The qualified time for soft surface virucidal disinfection is 10 minutes.
- h. In the section “**Cold / Flu**” add the text “on treated surfaces” to the claim: “helps stop the spread of the Cold and Flu Viruses”.
- i. In the section “**General**” on page 13 of 26, remove “(wherever)” from the claim: “kill(s) germs (whenever)(wherever) you need it”.
- j. In the section “**General**” on page 14 of 26, add the text “on treated surfaces” to the claim: “helps (aid(s)) in the reduction of cross-contamination of (germs)”.